

Kongeriget Danmark

Patent application No.:

PA 2002 01788

Date of filing:

19 November 2002

Applicant:

(Name and address)

Rhinometrics A/S

Industrivej 9

DK-3550 Lynge

Denmark

Title: Device for measuring in bodily cavities. (Indretning til måling i kropskaviteter)

IPC: A 61 B 8/12; A 61 B 5/085; A 61 B 5/107

This is to certify that the attached documents are exact copies of the above mentioned patent application as originally filed.



PRIORITY DOCUMENT

SUBMITTED OR TRANSMITTED IN COMPLIANCE WITH RULE 17.1(a) OR (b)

Patent- og Varemærkestyrelsen Økonomi- og Erhvervsministeriet

04 December 2003

Henrik Grye Skou





1

TITLE

Device for measuring in bodily cavities

BACKGROUND OF THE INVENTION

5

10

30

The present invention relates to the examination and measurement of constrictions or passages in cavities by means of acoustic reflectometry using a device comprising an electric signal source, a catheter to be introduced through an entrance to a cavity, a first transducer for transfer of an activation signal from the signal source to and through the catheter, a second transducer for reception of response signals from the catheter, the first and second transducers being connected with the, and a computer adapted for analysis of the response signals in relation to the activation signal.

- For examination and measurement of blockings, deformations, movements etc. in various human and animal cavities, e.g. pharynx, larynx and other air and alimentary passages, urinary passages, arteries etc. various methods are known.
- From US 5823965 a device and a method are known, which comprise a catheter with a
 flexible measuring zone. Transducers are provided for providing a reflectometric
 analysis of a bodily cavity.

SUMMARY OF THE INVENTION

The invention aims towards providing improvement in the measuring capability in such devices.

According to the invention this may be achieved by means of a device as defined in claim 1. Providing a pressure transducer which is adapted for obtaining low frequency pressure data from the cavity makes it possible to obtain these data simultaneously and hence make an analysis of the interaction of these different physical conditions giving rise to the different measurements.

The low frequency sensitive transducer may of a type sensitive to pressure alterations below 50 Hz, preferably below 10 Hz.

The transducer produces an output signal that is transmitted to the signal analysis device,

e.g. a computer, where this is sampled together with the reflectometry data obtained form
the reflectometry analysis.

The invention further relates to a method for obtaining dynamic data of the conditions in a bodily cavity, the method comprising obtaining reflectometric data on the shape of the bodily cavity and simultaneously obtaining values of low frequency pressure alterations in the bodily cavity.

10

15

25

After obtaining the data the method may comprise transmitting the data obtained to a signal processing device for simultaneous processing. Here the data obtained from the reflectometry and the low frequency may be used to provide corresponding area and pressure representations, e.g. in a coordinate system having pressure along one axis and area along another axis.

In preferred embodiments of the method, the cavity is an organic cavity, e.g. the respiratory passages, the blood or lymph tracts, the alimentary canal, or the urinary system or sections thereof of an animal or a human body.

Other features and advantages of the present invention will become apparent from the following description of embodiments of the invention, which refers to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a block diagram of the basic lay-out of the device according to the an embodiment of invention;

FIG. 2 is a perspective drawing of part of the catheter, at the spot where the measurement is made;

FIG. 3 is a perspective drawing of part of the catheter in another embodiment of the invention;

FIG. 4 is a sectional view of the catheter according to FIG. 3 in a sectional plane at right angles to the axis of the catheter;

FIG. 5 illustrates the placing of a catheter in the upper air passages with a patient being examined for tongue-fallback;

10

FIG. 6 illustrates the placing of a catheter in the upper air passages with a patient being examined for stertorous respiration.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

FIG. 1 shows the basic lay-out of the device according to the invention.

As seen in FIG. 1, there is shown a catheter 1, the design of which will be explained below. At its proximal end A, the catheter 1 of a manner known per se, not illustrated, is connected to auxiliary equipment used for inserting the catheter in, e.g., the air passages of a patient, through the mouth or the nostrils, or in the urinary system or an artery. The distal end of the catheter B, which after insertion, will be present in the cavity of the patient who undergoes an examination.

25

30

15

20

An electronic signal generator 2 is adapted to give an activation signal to a transducer 3 connected to the catheter 1. The signal generator 2 delivers the same signal to a signal analysis processor 4. A transducer 5 is connected to the catheter 1. When an excitation signal is transferred from the signal generator 2, via the transducer 3, to the interior of the catheter 1, this signal will propagate in the catheter, on to the distal end of the catheter, from where a response signal is sent back and received by the transducer 5 and from there led to the signal analysis processor 4. A further transducer is provided for obtaining low frequency pressure values in the bodily cavity. This transducer is sensitive

to very slow alterations in pressure values, which may arise from swallowing movements of a patients or other controlled or uncontrolled changes of the pressure conditions in the bodily cavity. The frequency of the pressure alterations obtained by the further transducer are below 50 Hz and most often below 10 Hz. A pump is shown for providing a pressure to the catheter. The invention also relates to a method for obtaining dynamic data of the conditions in a bodily cavity, where the method comprises obtaining reflectometric data on the shape of the bodily cavity and simultaneously obtaining values of low frequency pressure alterations in the bodily cavity. After obtaining the data the method may comprise transmitting the data obtained to a signal processing device for simultaneous processing. Here the data obtained from the reflectometry and the low frequency may be used to provide corresponding area and pressure representations, e.g. in a coordinate system having pressure along one axis and area along another axis.

The signal analysis processor 4 is connected to a computer 6 by means of which it is possible on a screen 7 to present an image, which illustrates the results of the examination and measurements made.

The transducer 3 can be an arbitrary type known per se, e.g. an electromagnetic transducer, an electrostatic transducer, a piezo-electric transducer, etc. Its task is to transform the electronic signal from the signal generator 2 into an excitation signal in the interior of the catheter 1.

The transducer 5 can also be of the above mentioned arbitrary type, e.g. a microphone, the purpose of which is to receive an acoustic response signal from the distal end of the catheter and to transform this response signal into an electric signal which is led to the signal analysis processor 4.

The analysis itself of the response signal in relation to the excitation signal belongs to a technique known per se.

30

10

15

20

25

A transducer 20 has been introduced from the outside through the outer chamber 12 and through the wall 15 so that the response signal receiving end 21 of the transducer 20 is

located in the lumen 11.

FIG. 5 illustrates the use of the catheter in order to determine the position of and measure the so-called tongue fallback with a patient, e.g. the situation where the patient's tongue narrows the upper air passages.

Here the catheter has been introduced through the nostrils and into the air passage. Part of the catheter is compressed by the rear end of the tongue in the zone D.

FIG. 6 illustrates the use of the catheter in order to determine the position of and measure the outbreak of vibrations in the soft palate (velum palatum).

FIG. 6 shows the situation illustrated in FIG. 5 as well as the situation where said soft parts of the palate compress the catheter in the zone E.

15

The mode of operation of the device according to the invention will be explained below.

While the known technique has the disadvantage that the measurements can be disturbed by crossmodes (e.g. cross resonances) which, e.g., is the case in examinations of the air passages and the lungs with a patient, the technique according to the invention has the essential advantage that it is the inner cavity of the catheter which constitutes the measurement cavity proper, which on occasion will be modified by, e.g., a constriction in the passage in which the catheter has been introduced. The construction of the catheter excludes the outbreak of cross resonances as in the known technique:

25

20

FIG. 6 illustrates as already mentioned the situation where a patient is to be examined for vibrations in the soft parts of the palate, e.g. typically stertorous respiration. The vibrations in the zone E will influence at least one of the outer chambers of the catheter and the measurement equipment can carry out the positioning and measurement.

30

Obviously medical or surgical considerations decide the choice of the inner and outer dimensions of the catheter which is the reason why the catheter is manufactured in different sizes (and lengths too), while the measurement equipment decides the upper

frequency limit, if a transient signal is used, as well as the other physical parameters.

A particular example of the use of the invention has already been mentioned.

Exact examinations of persons, whose air passages are blocked during their sleep and who can be described as having stertorous respiration, are naturally very difficult and through the ages many failed corrective operations have been made on these patients.

This is the reason why equipment which acoustically registers the stertorous respiration does not activate an alarm with sufficient security, as the non-occurrence of a "snoring sound" is either due to a quiet, steady respiration with a low regular flow, which is all right, or the air passages being blocked for a long time. This is where the risk lies.

An internal measurement has the advantage that the patient is not awakened during the measurements by the excitation signal and at the same time the measurements are not influenced to a large extent by the high tone sound spectrum of the snoring sounds.

15

20

25

30

A correct "tightening" through the nose happens automatically due to the reflectory swallowing, and a connection (transducer/microphone part) at the end which projects out of the nose can be made without problems.

It should also be noted that the measurement equipment (hardware/software) which adequately makes the measurements in each chamber and during the measurements changes the static pressure in each chamber can also concurrently give information about the elasticity of the tissue giving counter-pressure to the surface of the chambers.

By establishing a pressure in the catheter and a concurrent supply of acoustic energy in the infrasound band up to 200 Hz in the lumen and the chambers and a synchronization of this infrasound signal with the acoustic rhinometry (reflectometric) measurements, it is possible to obtain valuable information about the elasticity in the walls to which the catheterwall establishes a contact during the various pressure conditions.

Considering that these kinds of transducers, e.g. a piezoelectric transducer function in

both directions, e.g. being applied an electric voltage in order to give a pressure signal, or receiving a pressure signal and give an electric signal, it is obvious that instead of two transducers 3 and 5 in FIG. 1 it is in principle possible to use one single transducer, in which case the signal generator 2 should be electronically designed in such a way that, when operated from the analysis unit 4 and the computer 6, it firstly gives a transient signal and then transfers the response signal to the analysis unit. If a random or a pseudorandom signal is used as excitation signal, emitted continuously in the measurement period, two separate transducers will be used, as shown in FIG. 1.

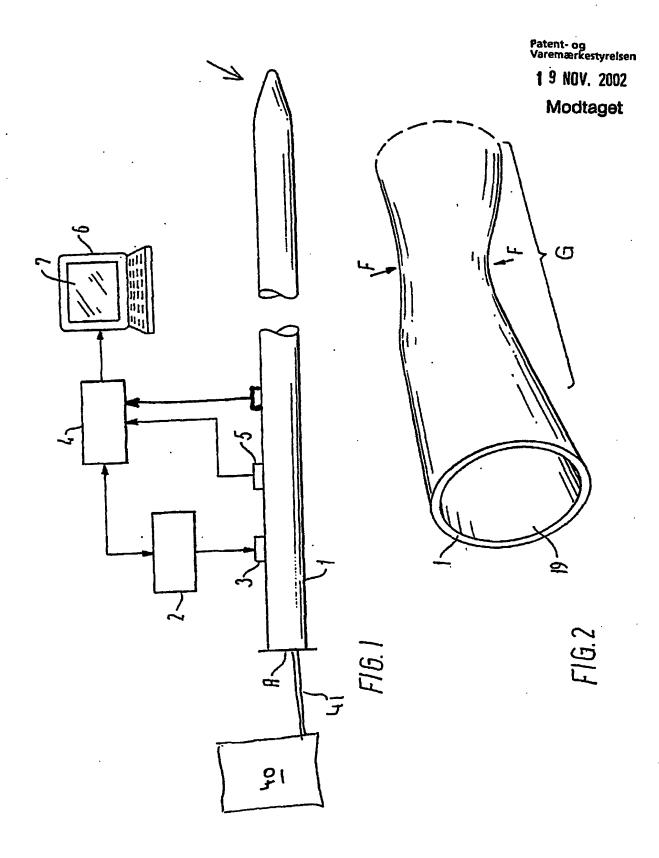
It should also be added that the invention also offers the possibility of making prostate or uterus examinations etc.

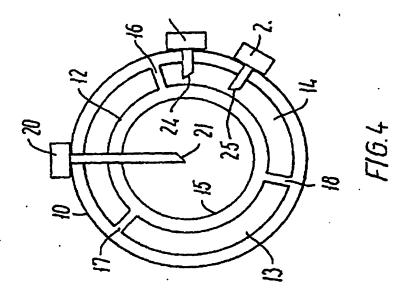
CLAIMS

- 1. A device for measuring in bodily cavities, the device comprising a flexible catheter for at least partial insertion into bodily cavity, a signal generator for generating an electric output signal, a transducer for transmitting an acoustic signal based on the electrical output signal into the catheter and a transducer for obtaining a reflection of the acoustic signal, a signal processing device for reflectometric analysis of the reflected signal, a further transducer for obtaining values of low frequency pressure alterations in the bodily cavity, where the output of the transducer obtaining the values of the low frequency pressure alterations is connected to a signal processing device.
- A device according to claim 1, where the transducer for obtaining values of low frequency pressure alterations in the bodily cavity is sensitive to frequencies
 below 50 Hz, preferably below 10 Hz.
- A method for obtaining dynamic data of the conditions in a bodily cavity, the method comprising obtaining reflectometric data on the shape of the bodily cavity and simultaneously obtaining values of low frequency pressure alterations in the bodily cavity.
 - 4. A method according to claim 3, comprising transmitting the data obtained to a signal processing device for simultaneous processing.
- 25 5. A method according to claim 3, where the data obtained from the reflectometry and the low frequency are used to provide corresponding area and pressure representations.

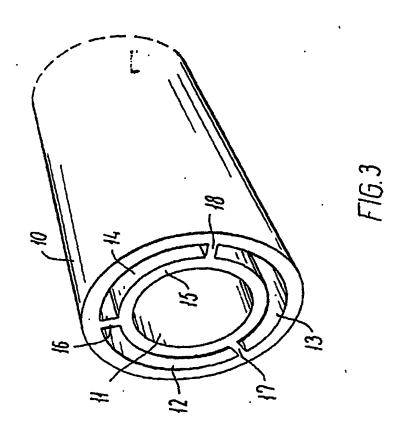
ABSTRACT

The invention relates to a device for measuring in bodily cavities, the device comprising a flexible catheter for at least partial insertion into bodily cavity, a signal generator for generating an electric output signal, a transducer for transmitting an acoustic signal based on the electrical output signal into the catheter and a transducer for obtaining a reflection of the acoustic signal, a signal processing device for reflectometric analysis of the reflected signal, a further transducer for obtaining values of low frequency pressure alterations in the bodily cavity, where the output of the transducer obtaining the values of the low frequency pressure alterations is connected to a signal processing device. The invention further relates to a method for obtaining dynamic data of the conditions in a bodily cavity, the method comprising obtaining reflectometric data on the shape of the bodily cavity and simultaneously obtaining values of low frequency pressure alterations in the bodily cavity.





Patent- og Varemærkestyrelsen 1 9 NOV. 2002 Modtaget



F/G.6

This Page is Inserted by IFW Indexing and Scanning Operations and is not part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:
☐ BLACK BORDERS
☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
☐ FADED TEXT OR DRAWING
BLURRED OR ILLEGIBLE TEXT OR DRAWING
☐ SKEWED/SLANTED IMAGES
☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
☐ GRAY SCALE DOCUMENTS
☐ LINES OR MARKS ON ORIGINAL DOCUMENT
☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
□ other:

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.